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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,958	07/30/2003	Thomas Wuske	71072	1769

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EXAMINER	
MOSS, KERI A	

ART UNIT	PAPER NUMBER
1743	

MAIL DATE	DELIVERY MODE
08/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/630,958	WUSKE ET AL.	
	Examiner	Art Unit	
	Keri A. Moss	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,9-11,13,14,16-24,26-28 and 31-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,3,9-11,13,14,16-24,26-28 and 31-35* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims **1 and 3**, drawn to a device for collecting and releasing sample comprising a sample collector, porous and dimensionally stable tip wherein the tip has an indicator zone including a moisture indicator being one of indicator dye or a material that expands; and a pressure means displaceable for generating overpressure, classified in class 73, subclass 863.51.

II. Claims **9**, drawn to a system with a device for collecting and releasing sample comprising a porous and dimensionally stable tip wherein the tip has an indicator zone including a moisture indicator; a pressure means for generating an overpressure; a beaker-shaped reagent container wherein the reagent container and the tip fully enclose a volume classified in class 422, subclass 102.

III. Claims **10-11, 13-14 and 16-17**, drawn to a process for collecting and releasing sample wherein the process includes a collector with a porous and incompressible tip wherein the tip comprises an indicator zone having a moisture indicator being one of an indicator dye or a material that

expands in the presence of moisture; and a pressure means that generates an overpressure in the pores of the sample tip, classified in class 436, subclass 180.

IV. Claims **18-24 and 26-28**, drawn to a system for collecting sample comprising a collector with a cylindrical shape and first and second axial ends, a tip at the first end having a porous and dimensionally stable tip wherein the tip material collects sample by capillary action and the tip extends out of the first axial end, the tip defining a cavity and containing an indicator zone having a moisture indicator; and a pressure device connectible to the sample collector, classified in class 73, subclass 864.02.

V. Claim **31**, drawn to a process for collecting and releasing sample wherein the process includes a porous and dimensionally stable tip that has an indicator zone including a moisture indicator; a means for generating an overpressure; a sealing lip; a reagent container with a chamber wherein the sealing lip, the tip and the chamber fully enclose a volume; the reagent chamber contains reagent, classified in class 73, subclass 864.91.

VI. Claim **32**, drawn to a sampling system comprising a porous and incompressible sampling tip wherein the tip collects sample by capillary action and wherein the tip does not comprise a moisture indicator; a pressure device at the second axial end of the collector; and a filter mixer, classified in class 422, subclass 100.

VII. Claim **33**, drawn to a sampling system comprising a porous and incompressible sampling tip wherein the tip collects sample by capillary action and wherein the tip does not comprise a moisture indicator; a puncturing device at the second axial end of the collector; and a cylinder defining a chamber connectible with the sample collector for generating an overpressure, classified in class 73, subclass 864.81.

VIII. Claim **34**, drawn to a sampling system comprising a porous and incompressible sampling tip wherein the tip collects sample by capillary action and wherein the tip does not comprise a moisture indicator; a pressure device including a plunger; and a puncturing device arranged at one end of the plunger, classified in class 73, subclass 864.13.

IX. Claim **35**, drawn to a sampling system comprising a porous and incompressible sampling tip wherein the tip collects sample by capillary action and wherein the tip does not comprise a moisture indicator; a pressure device arranged at the second axial end of the collector; and a reagent container wherein the reagent container and a sealing lip fully enclose a volume when the sampling tip is inserted into the chamber, classified in 422, subclass 63.

The inventions are distinct in the following ways:

3. Inventions **I and II-IX** are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the

different inventions designs as group I requires a displaceable pressure means for generating an overpressure while the other groups do not require a displaceable pressure means. Thus, groups II-IX encompass a much broader range of pressure means, such as air pumps.

4. Inventions **I/II and III-IX** are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because a tip that is dimensionally stable is not inherently incompressible. For example, a sponge is dimensionally stable but not incompressible. The subcombination has separate utility such as for a reusable tip, whereas a dimensionally stable sponge is capable of a single sample collecting use.

The examiner has required restriction between combination and subcombination inventions. Where applicant elects a subcombination, and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such

claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

5. Inventions **I/II/IV/VI/VII/VIII/IX and III/V** are related as product and process of use, respectively. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the process of group III can be used only with porous and dimensionally stable tips, as opposed to groups I-II, which can be used with a compressible tip, such as a sponge. In addition, the products of groups IV and VI-IX can be used in a materially different process, such as one that collects the sample into a cavity within the tip. In the instant case, the products of groups I,II,IV and VI-IX can be used in a materially different process, such as one that does not involve a reagent container that with the sampling tip and sealing lip fully encloses a volume. An example is that the products can be used to release the sample immediately after collection directly into an analytical device such as a test strip, or into a device as claimed.

6. Inventions **III and V** are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the

particulars of the subcombination as claimed because group III does not require the particulars of group V's providing a sealing lip or reagent container which fully enclose a volume with the sampling tip. The subcombination has separate utility such as providing a transportable sample collector that does not leak.

The examiner has required restriction between combination and subcombination inventions. Where applicant elects a subcombination, and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

7. Inventions **IV and VI-IX** are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In the instant case, subcombination IV has separate utility such as identifying by means of a moisture indicator when a predetermined amount sample of liquid has been taken up by the collector. See MPEP § 806.05(d).

The examiner has required restriction between subcombinations usable together. Where applicant elects a subcombination and claims thereto are subsequently found

allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

8. Inventions **VI and VII and VIII and IX** are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the three inventions as claimed each have materially different modes of operation as each group claims a different mode of combining the sample with a reagent. The specification teaches the addition of only one reagent. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

9. Inventions **VI and IX** are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not disclosed as capable of use together as they are two

different enclosures for the sampling tip and are described as separate embodiments (see paragraphs [0017] and [0018]) and are not disclosed in the drawings as capable of use together. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Election of Species

10. This application contains claims directed to the following patentably distinct species: 1) the filter mixer of Claim **19** and 2) the sealing lip and reagent container of Claims **26-28**. The species are independent or distinct because they are described in the specification as distinct embodiments (see paragraphs [0017] and [0018]).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 18 is generic.

11. This application contains claims directed to the following patentably distinct species: 1) the sample collector with a puncturing device at the second axial end of the collector of claims **20-21** and 2) the sample collector comprising a plunger with a puncturing device of claims **23 and 24**. The species are independent or distinct because they are described within the specification as distinct embodiments (see paragraphs [0039] and [0040]).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 18 is generic.

12. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

13. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

14. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keri A. Moss whose telephone number is 571-272-8267. The examiner can normally be reached on 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)272-1700. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Keri A. Moss
Examiner
Art Unit 1743

KAM 8/27/07

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